



## ENVIRONMENTAL PROTECTION AGENCY

[EPA-HQ-OAR-2006-0525; FRL- 9782-3]

### **Proposed Information Collection Request; Comment Request; Registration of Fuels and Fuel Additives - Health-Effects Research Requirements for Manufacturers; EPA ICR No. 1696.07**

**AGENCY:** Environmental Protection Agency (EPA).

**ACTION:** Notice.

**SUMMARY:** The Environmental Protection Agency is planning to submit an Information Collection Request (ICR), Registration of Fuels and Fuel Additives – Health-Effects Research Requirements for Manufacturers, EPA ICR No. 1696.07, OMB Control No. 2060-0297, to the Office of Management and Budget (OMB) for review and approval in accordance with the Paperwork Reduction Act (44 U.S.C. 3501 *et seq.*). Before doing so, EPA is soliciting public comments on specific aspects of the proposed information collection as described below. This is a proposed extension of the ICR, which is currently approved through August 31, 2013. An Agency may not conduct or sponsor and a person is not required to respond to a collection of information unless it displays a currently valid OMB control number.

**DATES:** Comments must be submitted on or before [insert date 60 days after publication in the Federal Register].

**ADDRESSES:** Submit your comments, referencing Docket ID No. EPA-HQ-OAR-2006-0525, online using [www.regulations.gov](http://www.regulations.gov) (our preferred method), by email to [a-and-r-docket@epa.gov](mailto:a-and-r-docket@epa.gov), or by mail to: EPA Docket Center, Environmental Protection Agency, Mail Code 28221T, 1200 Pennsylvania Ave., NW, Washington, DC 20460.

EPA's policy is that all comments received will be included in the public docket without

change including any personal information provided, unless the comment includes profanity, threats, information claimed to be Confidential Business Information (CBI) or other information whose disclosure is restricted by statute.

**FOR FURTHER FORMATION CONTACT:** James W. Caldwell, Compliance Division, Office of Transportation and Air Quality, Mailcode: 6406J, Environmental Protection Agency, 1200 Pennsylvania Ave., NW, Washington, DC 20460; telephone number: (202) 343-9303; fax number: (202) 343-2802; email address: [caldwell.jim@epa.gov](mailto:caldwell.jim@epa.gov).

#### **SUPPLEMENTARY INFORMATION:**

Supporting documents which explain in detail the information that the EPA will be collecting are available in the public docket for this ICR. The docket can be viewed online at [www.regulations.gov](http://www.regulations.gov) or in person at the EPA Docket Center, EPA West, Room B102, 1301 Constitution Ave., NW, Washington, DC. The telephone number for the Docket Center is 202-566-1744. For additional information about EPA's public docket, visit <http://www.epa.gov/dockets>.

Pursuant to section 3506(c)(2)(A) of the PRA, EPA is soliciting comments and information to enable it to: (i) evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the Agency, including whether the information will have practical utility; (ii) evaluate the accuracy of the Agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (iii) enhance the quality, utility, and clarity of the information to be collected; and (iv) minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated electronic, mechanical, or other technological collection techniques or other forms of information technology, e.g., permitting

electronic submission of responses. EPA will consider the comments received and amend the ICR as appropriate. The final ICR package will then be submitted to OMB for review and approval. At that time, EPA will issue another Federal Register notice to announce the submission of the ICR to OMB and the opportunity to submit additional comments to OMB.

*Abstract:* In accordance with the regulations at 40 CFR 79, Subparts A, B, C, and D, Registration of Fuels and Fuel Additives, manufacturers (including importers) of motor-vehicle gasoline, motor-vehicle diesel fuel, and additives for those fuels, are required to have these products registered by the EPA prior to their introduction into commerce. Registration involves providing a chemical description of the fuel or additive, and certain technical, marketing, and health-effects information. The development of health-effects data, as required by 40 CFR 79, Subpart F, is the subject of this ICR. The information collection requirements for Subparts A through D, and the supplemental notification requirements of Subpart F (indicating how the manufacturer will satisfy the health-effects data requirements) are covered by a separate ICR (EPA ICR Number 309.13, OMB Control Number 2060-1050). The health-effects data will be used to determine if there are any products which have evaporative or combustion emissions that may pose an unreasonable risk to public health, thus meriting further investigation and potential regulation. This information is required for specific groups of fuels and additives as defined in the regulations. For example, gasoline and gasoline additives which consist of only carbon, hydrogen, oxygen, nitrogen, and/or sulfur, and which involve a gasoline oxygen content of less than 1.5 weight percent, fall into a “baseline” group. Oxygenated additives, such as ethanol, when used in gasoline at an oxygen level of at least 1.5 weight percent, define separate “nonbaseline” groups for each oxygenate. Additives which contain elements other than carbon, hydrogen, oxygen, nitrogen, and sulfur fall into separate “atypical” groups. There are similar grouping requirements for diesel fuel and diesel fuel additives.

Manufacturers may perform the research independently or may join with other manufacturers to share in the costs for each applicable group. Several research consortiums (groups of manufacturers) have been formed. The largest consortium, organized by the American Petroleum Institute (API), represents most of the manufacturers of baseline gasoline, baseline diesel fuel, baseline fuel additives, and the prominent nonbaseline oxygenated additives for gasoline. The research is structured into three tiers of requirements for each group. Tier 1 requires an emissions characterization and a literature search for information on the health effects of those emissions. Voluminous Tier 1 data for gasoline and diesel fuel were submitted by API and others in 1997. Tier 1 data have been submitted for biodiesel, water/diesel emulsions, several atypical additives, and renewable gasoline and diesel fuels. Tier 2 requires short-term inhalation exposures of laboratory animals to emissions to screen for adverse health effects. Tier 2 data have been submitted for baseline diesel, biodiesel, and water/diesel emulsions. Alternative Tier 2 testing can be required in lieu of standard Tier 2 testing if EPA concludes that such testing would be more appropriate. EPA reached that conclusion with respect to gasoline and gasoline-oxygenate blends, and alternative requirements were established for the API consortium for baseline gasoline and six gasoline-oxygenate blends. Alternative Tier 2 requirements have also been established for the manganese additive MMT manufactured by the Afton Chemical Corporation (formerly the Ethyl Corporation). Tier 3 provides for follow-up research, at EPA's discretion, when remaining uncertainties as to the significance of observed health effects, welfare effects, and/or emissions exposures from a fuel or fuel/additive mixture interfere with EPA's ability to make reasonable estimates of the potential risks posed by emissions from a fuel or additive. To date, EPA has not imposed any Tier 3 requirements. Under regulations promulgated pursuant to Section 211 of the Clean Air Act, (1) submission of the health-effects information is necessary for a manufacturer to obtain registration of a motor-

vehicle gasoline, diesel fuel, or fuel additive, and thus be allowed to introduce that product into commerce, and (2) the information shall not be considered confidential.

*Form Numbers:* None.

*Respondents/affected entities:* Manufacturers of motor-vehicle gasoline, motor-vehicle diesel fuel, and additives for those fuels.

*Respondent's obligation to respond:* Mandatory per 40 CFR 79.

*Estimated number of respondents:* 2.

*Frequency of response:* On occasion.

*Total estimated burden:* 19,200 hours per year. Burden is defined at 5 CFR 1320.03(b).

*Total estimated cost:* \$2 million per year, includes \$0.5 million annualized capital or operation & maintenance costs.

*Changes in Estimates:* There is a decrease of 2,000 hours in the total estimated respondent burden compared with the ICR currently approved by OMB. This decrease is due to the conclusion of a testing program included in the previous ICR.

Dated: February 13, 2013.

**Byron J. Bunker, Director,**  
**Compliance Division.**

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